Plasma, that test reactive by a screening test for syphilis as required under paragraph (i) of this section if, consistent with § 640.5 of this chapter, the donation is further tested by an adequate and appropriate test which demonstrates that the reactive screening test is a biological false positive. You must label the blood or blood components with both test results.

(vii) You may use Source Plasma from a donor who tests reactive by a screening test for syphilis as required under § 610.40(i) of this chapter, if the donor meets the requirements of § 640.65(b)(2) of this chapter.

(i) *Syphilis testing.* In addition to the testing otherwise required under this section, you must test by a serological test for syphilis under §§ 640.5(a), 640.14, 640.23(a), 640.33(a), 640.53(a), and 640.65(b)(2) of this chapter.

[66 FR 31162, June 11, 2001]

EFFECTIVE DATE NOTE: At 77 FR 18, Jan. 3, 2012, § 610.40 was amended by revising paragraphs (h)(2)(ii)(B) and (i), effective July 2, 2012. For the convenience of the user, the revised text is set forth as follows:

§ 610.40 Test requirements.

* * * * *

(h) * * *
(2) * * *
(ii) * * *

(B) You must appropriately label such blood or blood components as required under § 606.121 of this chapter, and with the ''BIOHAZARD'' legend;

* * * * *

(i) *Syphilis testing.* In addition to the testing otherwise required under this section, you must test by a serological test for syphilis under §§ 640.5(a), 640.14, 640.23(a), 640.33(a), 640.53(a), and 640.65(b)(1) and (b)(2) of this chapter.

§ 610.41 Donor deferral.

(a) You, an establishment that collects human blood or blood components, must defer donors testing reactive by a screening test for evidence of infection due to a communicable disease agent(s) listed in § 610.40(a) or reactive for a serological test for syphilis under § 610.40(i), from future donations of human blood and blood components, except:

(1) You are not required to defer a donor who tests reactive for anti-HBc or anti-HTLV, types I or II, on only one occasion. When a supplemental (additional, more specific) test for anti-HBc or anti-HTLV, types I and II, has been approved for use under § 610.40(e) by FDA, such a donor must be deferred;

(2) A deferred donor who tests reactive for evidence of infection due to a communicable disease agent(s) listed in § 610.40(a) may serve as a donor for blood or blood components shipped or used under § 610.40(h)(2)(ii);

(3) A deferred donor who showed evidence of infection due to hepatitis B surface antigen (HBsAg) when previously tested under § 610.40(a), (b), and (e) subsequently may donate Source Plasma for use in the preparation of Hepatitis B Immune Globulin (Human) provided the current donation tests nonreactive for HBsAg and the donor is otherwise determined to be suitable;

(4) A deferred donor, who otherwise is determined to be suitable for donation and tests reactive for anti-HBc or for evidence of infection due to HTLV, types I and II, may serve as a donor of Source Plasma;

(5) A deferred donor who tests reactive for a communicable disease agent(s) described under § 610.40(a) or reactive with a serological test for syphilis under § 610.40(i), may serve as an autologous donor under § 610.40(d).

(b) A deferred donor subsequently may be found to be suitable as a donor of blood or blood components by a requalification method or process found acceptable for such purposes by FDA. Such a donor is considered no longer deferred.

(c) You must comply with the requirements under §§ 610.46 and 610.47 when a donor tests reactive by a screening test for HIV or HCV required under § 610.40(a) and (b), or when you are aware of other reliable test results or information indicating evidence of HIV or HCV infection.

[66 FR 31164, June 11, 2001, as amended at 72 FR 48798, Aug. 24, 2007]

§ 610.42 Restrictions on use for further manufacture of medical devices.

(a) In addition to labeling requirements in subchapter H of this chapter, when a medical device contains human